



JAN 16 2001

K 003136

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: Ocular Sciences, Inc.
Address: 475 Eccles Av.
South San Francisco, CA 95014
Phone: (415) 583-1400
Fax: (415) 583-1108

CONTACT PERSON:

Richard E. Lippman, O.D., F.A.A.O.
Official Representative and Correspondent
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway Suite 625
Rockville, MD 20852

DATE SUMMARY PREPARED:

October 2, 2000

TRADE NAME:

BIOMEDICS[®] 52 (ocufilcon B) UV Blocking Daily Wear
soft (Hydrophilic) Contact Lens

COMMON NAME:

contact lens

ESTABLISHMENT REGISTRATION: 2936790

SUBSTANTIALLY EQUIVALENT TO:

The BIOMEDICS[®] 52 (ocufilcon B) UV Blocking Daily Wear Contact Lens with In-Monomer Tint is equivalent to the daily wear lens of the same material but of a modified water content as cleared in K984046, K942214, P890023/S26, P890023/S4, and K972303 in-monomer visibility tint cast molded ocufilcon D for daily wear currently marketed by Ocular Sciences, Inc.

The BIOMEDICS[®] 52 (ocufilcon B) UV Blocking Daily Wear contact lens is substantially equivalent to the indication for use of the BIOMEDICS[®] 55 (ocufilcon D) In Monomer Tint ocufilcon D cast molded contact lens marketed for use in the U.S. by Ocular Sciences, Inc. cleared under K984046 and K972303. Additionally, the subject contact lens is equivalent and

has similar and equivalent characteristics and properties as the clear BIOMEDICS[®] 55 (ocufilcon D) cast molded contact lens, cleared under K942214, and P890023/S26. The cast molding process was approved under P890023/S4. This lens is in the Lens Group IV high water ionic group as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the BIOMEDICS[®] 52 (ocufilcon B) UV visibility tint cast molded Ocular Sciences, Inc. contact lens are substantially equivalent to both the clear and tinted versions of the BIOMEDICS[®] 55 (ocufilcon D) ocufilcon D cast molded contact lenses, as well as to Ocu-Ease Optical, Ocu-Flex 53 (ocufilcon B) daily wear contact lenses cleared for marketing under K960291, March 25, 1996.

DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and other monomeric ingredients including a proprietary ultraviolet absorber, crosslinked with EDGMA and other components which yield the appearance of lenses which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power which is to correspond to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens which is generally of a diameter greater than 6mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

INDICATIONS FOR USE:

Spherical:

Biomedics[®] 52 (ocufilcon B) UV Blocking Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

Toric:

Biomedics[®] 52 (ocufilcon B) UV Blocking Contact Lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 10.00 diopters.

The lenses may be prescribed for Daily Wear in not-aphakic persons. The eye care practitioner may prescribe the contact lens for either single use disposable wear or for frequent replacement wear, with cleaning, disinfection, and scheduled replacement (SEE WEARING SCHEDULE). When prescribing for frequent replacement wear, the contact lens may be disinfected using a

chemical (not heat) disinfecting system.

Biomedics[®] 52 (ocufilcon B) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye

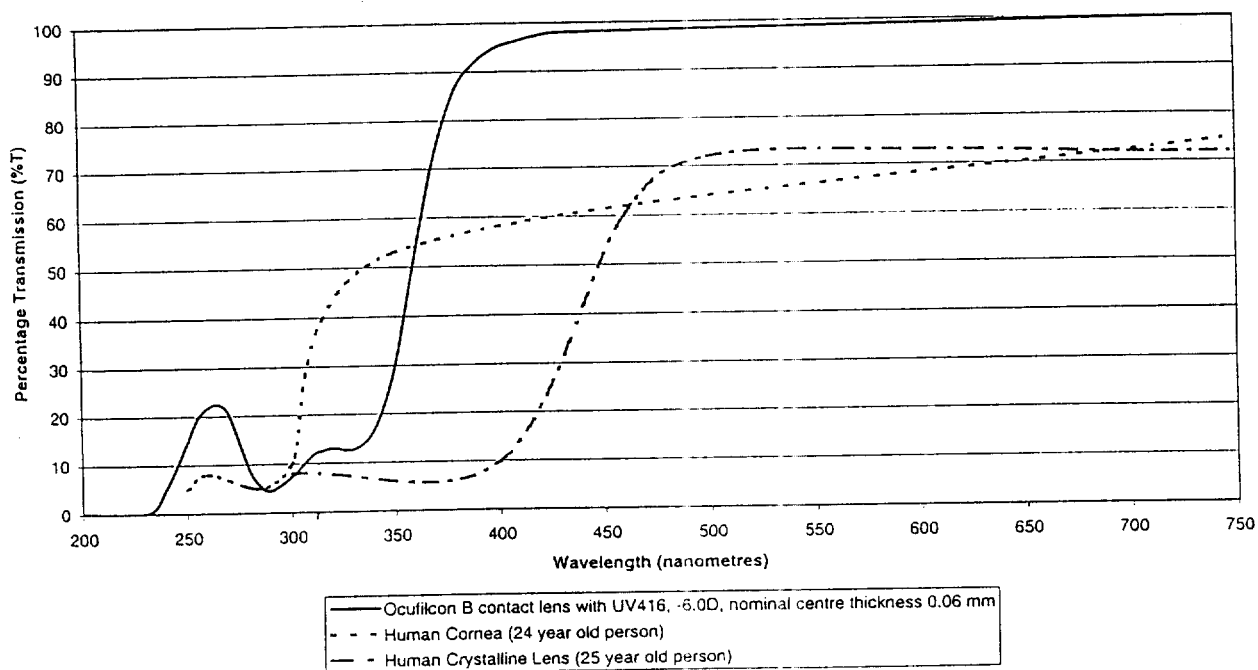
PARAMETERS AVAILABLE:

Base Curves:	6.50 mm to 10.8 mm
Diameters:	12.5 mm to 18.0 mm
Powers:	-10.00 to +10.00 Diopters sphere
Cylinder Power:	-00.25 to -10.00 Diopters
Center Thickness:	0.025 mm to 0.27 mm depending on power
Tint:	Blue Visibility tint

ULTRAVIOLET TRANSMITTANCE CURVES

The following graph represents the transmittance of ultraviolet light in the UVA and UVB range as well as light transmittance through the visual spectrum, as compared to the human cornea and crystalline lens:

Typical Transmittance Profile of -6.00 D Ocufilcon B Hydrophilic Daily Disposable Contact Lens with UV416 versus a Human Cornea and a Human Lens



The average transmittance of UVA and UVB ultraviolet radiation through the lenses across the range of thinnest lenses available is as follows:

	<u>UVA</u>	<u>UVB</u>
Range: -0.75 to -6.00D	21.0%	4.4%

PRECLINICAL INFORMATION

A battery of preclinical tests including toxicological analyses of Ocular Irritation, Cytotoxicity, and Systemic Toxicity were conducted on the material in animals. The results of these tests indicated that the finished materials or extracts of the finished materials were non-toxic to the tissues of the animals which were tested. Residuals of chemical monomers and the UV additive were evaluated and found to be of extremely low levels for the product monomers, and undetectable for the UV additive, to the sensitivity of the instrumentation used to calculate such residuals.

The physical, optical and chemical properties of the lens indicate that the device is substantially equivalent to the parent device of the marketed lens (ocufilcon D) material. The oxygen permeability of the material is $22.8 \times 10^{-11} \text{ (cm}^2\text{/sec)(mL O}_2\text{/mL x mm Hg)}$; a water content of 52%, a refractive index of 1.415; light transmittance of 97.7%.

Other physical characteristics of the device were equivalent to the company's prior marketed lenses to which this lens is compared.

The lens characteristics place it in Category IV (high water, ionic) and the device is compatible with all soft contact lens solutions available on the market for cleaning, rinsing and disinfection.

CLINICAL INFORMATION

There was no clinical investigation of this lens as the characteristics of the device are substantially equivalent to the device from which the lens was modified. The safety information provided and physical, optical and chemical parameters of the lens are substantially equivalent to lenses already having had clinical evaluation.

LABELING

The Biometric[®] 52 (ocufilcon B) UV Blocking IMT Visibility Tint Contact Lens for Daily Wear is provided to the user with a Package Insert, Patient Instruction Booklet for either Daily Disposable or Scheduled Replacement, and a Practitioner Fitting Guide. These materials are also available from the company. The address is as follows:

Ocular Sciences, Inc.
475 Eccles Ave.
South San Francisco, CA 94080
(650) 583-1400



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2001

Ocular Sciences/American Hydron, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K003136

Trade Name: Biomedics^R 52 (ocufilcon B) UV Blocker Daily Wear Contact Lens
Regulatory Class: II
Product Code: LPL
Dated: December 21, 2000
Received: December 27, 2000

Dear Dr. Lippman:

We have reviewed your Section 510(k) ~~notification of intent~~ to market the ~~device referenced~~ above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices ~~marketed in interstate commerce prior to May 28, 1976~~, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for ~~annual registration~~, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your ~~device~~ can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Richard E. Lippman, O.D., F.A.A.O.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive style with a large, stylized "A" and "R".

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K003136

Device Name: Biomedics^R 52 (ocufilcon B) UV Blocking Daily Wear Contact Lens

Indications for Use:

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Biomedics^R 52 (ocufilcon B) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

Additional Claims:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

Daniel W. C. Brown M.D.
(Division Sign-Off)

Division of Ophthalmic Devices

Over-the-Counter Use JS

(Optional Format 1-2-96)

510(k) Number K003136

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